



JAN 25 2005

Mailed: January 25, 2005

Gregg C. Benson  
Pfizer, Inc.  
Patent Department  
Eastern Point Road  
Groton CT 06340Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,959,366

## NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,959,366, which claims the human drug product TIKOSYN® (methanesulfonamide) and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be five years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of five years.

Under 35 U.S.C. § 156(c), the period of extension is calculated using the Food and Drug Administration's determination of the length of the regulatory review period as published in the Federal Register of April 18, 2003 (68 Fed. Reg. 19212).

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,778 - 56) + 572 \\ &= 1,933 \text{ days}\end{aligned}$$

Since the regulatory review period began August 1, 1990, before the patent issue date (September 25, 1990), the period during the regulatory review period on or before the issue date of the patent has been subtracted from the "testing phase" in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation, however, because the patent was issued after the date of enactment (September 24, 1984) of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,959,366
Granted:	September 25, 1990
Original Expiration Date <sup>1</sup> :	September 25, 2007
Applicant:	Cross, et al.

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).


Owner of Record: Pfizer Inc.  
Title: ANTI-ARRHYTHMIC AGENTS  
Classification: 514/239.5  
Product Trade Name: TIKOSYN® (methanesulfonamide)  
Term Extended: Five years  
Expiration Date of Extension: September 25, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents  
Mail Stop Patent Ext.  
P.O. Box 1450  
Alexandria, VA 22313-1450

By FAX: (703) 273-7744  
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at 571-272-7744.

  
Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

RE: TIKOSYN® (methanesulfonamide)  
FDA Docket No.: 00N-1248

Attention: Claudia Grillo